A Prospective, Randomized, Controlled Trial of the Treatment of Anterior Vaginal Wall Prolapse: Medium Term Followup

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Abbreviations and Acronyms

AVW = anterior vaginal wall
CONSORT = Consolidated Standards of Reporting Trials
ICIQ = International Consultation on Incontinence Questionnaire
ICS = International Continence Society
IUGA = International Urogynecology Association
OAB = overactive bladder
OAB-V8 = OAB Questionnaire-Validated 8
PM = polypropylene mesh
POP = pelvic organ prolapse
POP-Q = POP quantification system
QOL = quality of life
SF = UI Short Form
UI = urinary incontinence
VS = vaginal symptom
VSS = VS score

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Purpose: We compared the efficacy and safety of anterior colporrhaphy with transvaginal polypropylene mesh insertion for anterior vaginal wall prolapse at medium term followup.

Materials and Methods: In this prospective, randomized, controlled trial 100 women with stage II or greater anterior vaginal wall prolapse assessed by POP-Q were randomized to anterior colporrhaphy (controls) or mesh insertion. Anatomical outcomes were assessed by POP-Q measurement and prolapse stage. Subjective outcomes and quality of life impact were evaluated by ICIQ questionnaires. We evaluated the procedure safety profile according to intraoperative complication rates throughout followup.

Results: In the mesh and control groups 42 and 50 women completed the 24-month followup. Point Ba did not significantly differ between the groups at baseline but at 24-month followup it had significantly improved in the mesh group compared to controls. However, no difference was found between the groups when considering 2 cure criteria on prolapse stage and subjective parameters. Asymptomatic mesh exposure developed on the anterior vaginal wall prolapse in 7 patients (16.4%) in the mesh group. Minor mesh related complications consisted of mesh exposure, prepubic ecchymosis and groin pain, of which most were treated conservatively. Urinary retention was treated surgically.

Conclusions: Nazca TC™ and anterior colporrhaphy provided good overall anatomical outcomes during a minimum 24-month followup. Vaginal and urinary symptoms, and quality of life improved postoperatively in each group. From the patient perspective Nazca TC did not show superior overall outcomes compared to anterior colporrhaphy performed with or without a retropubic sling.

Key Words: urinary bladder, female, pelvic organ prolapse, cystocele, surgical mesh

Polypropylene mesh interposition to correct AVW prolapse was first proposed in 1998 to improve unsatisfactory outcomes after anterior colporrhaphy.[1] Most published prospective studies show a high anatomical success rate for mesh insertion at short-term followup.[2–5] Conversely a recent meta-analysis indicated that using mesh in anterior compartment surgeries produces improved anatomical repair but no improvement in functional outcomes.[6] Furthermore, complication rates and

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the impact of surgery on bladder function and QOL are poorly reported. It was recommended that trials should be done to assess these outcomes for at least 2 years.

We compared the efficacy and safety of transvaginal synthetic mesh insertion for AVW prolapse with anterior colporrhaphy at 24-month followup. We used objective and subjective outcomes as well as QOL and safety profile assessments. One-year outcomes were reported previously.[7]

MATERIALS AND METHODS

This was a medium term, primary analysis of a prospective, randomized, controlled study performed at a tertiary urogynecology referral center in São Paulo, Brazil, between February 2008 and December 2010. The Federal University of Sao Paulo research ethics committee approved the protocol. The study is registered with ReBEC (Brazilian Clinical Trials Registry, http://www.ensaiosclinicos.gov.br/, code RBR-7M2XDY).

Women 45 years old or older with stage II or greater AVW prolapse according to POP-Q[8] without previous surgical correction or with previous surgical treatment of AVW prolapse without PM were selected for study inclusion. Exclusion criteria, sample size calculation, blinding and randomization processes,[9] and the traditional anterior colporrhaphy surgical technique[3] were previously reported.[7] Women were randomly distributed to a PM group of 45 treated with a PM implant and a control group of 55 treated with anterior colporrhaphy without PM.

Preoperative and Postoperative Assessments

Methods, definitions and units were applied according to ICS and IUGA standards.[10] Data included age, race (white vs nonwhite), occupation (retired vs working), family income per month (1 or 2 vs more than 3 wages), diabetes (no vs yes), hypertension (no vs yes), stress test (negative vs positive), parity, number of deliveries, body mass index (kg/m^2), hormonal status (premenopausal vs postmenopausal), previous hysterectomy (no vs yes), POP stage and POP-Q points. Clinical categories were used to evaluate patient hormonal status. Women with more than 12 months of amenorrhea were considered to be postmenopausal. We conceptualized, developed and performed all study steps, including surgical procedures, and preoperative and postoperative assessments. Preoperatively patients underwent urodynamics using the Dynapack MPX 816 (Dynamed, São Paulo, Brazil) according to Urodynamic Society recommendations.[11]

Questionnaires

The ICS ICIQ-SF is a questionnaire validated for Portuguese that evaluates the UI impact on QOL.[12] The final score ranges from 0 to 21 with increasing scores indicating a worse impact of UI on QOL. A final score of 0 indicates no UI and a final score of 3 or greater indicates UI.

The OAB-V8 is a questionnaire validated for Portuguese that evaluates lower urinary tract symptoms.[13] The final score ranges from 0 to 48 with increasing scores indicating worse symptoms. A final score of 0 indicates no OAB symptoms and a final score of 1 or greater indicates OAB symptoms.

The ICIQ-VS is a questionnaire validated for Portuguese that evaluates pelvic floor symptoms.[14] The VSS ranges from 0 to 53 with outcomes shown as a VSS of 0—no VS, or 1 or greater—VSs. The QOL score ranges from 0 to 10 with increasing scores indicating a worse QOL impact. A QOL score of 0 indicates no QOL impact and a QOL score of 1 or greater indicates a QOL impact.

Outcomes and Safety Evaluation

The primary study outcome was the difference in anatomical success between the 2 interventions, defined as AVW at stages 0 and I (POP-Q Ba −2 or less) at 24-month followup according to ICS criteria. We also analyzed anatomical data using point Ba −1 or less to indicate success because this less stringent cure criterion is currently under discussion.[15] Secondary outcomes were to compare the groups for subjective vaginal and urinary symptoms, QOL, the group effect as well as safety, including intraoperative and postoperative complication rates. Symptomatic POP recurrence was defined as VSS greater than 0. Complications related or unrelated to the mesh implant were classified according to the IUGA/ICS terminology and classification report.[16]

Trocar Guided Nazca TC

The Nazca TC device contains type I monofilament and macroporous PM as well as 1 prepubic and 2 transobturator needles. Briefly, a midline incision is made in the AVW followed by pubovesicocervical fascia dissection.[17] Prepubic needles are introduced through the vaginal incision and directed toward 2 corresponding 5 mm suprapubic skin incisions. The mesh arms are delivered bilaterally, creating a backboard support for the mid urethra. The transobturator needles are inserted at the genitofemoral fold in outside-in fashion, exiting closest to the ischial spine through the vaginal opening from each side. The transobturator arm is connected to the needle and the PM is delivered through a 5 mm genitofemoral skin incision bilaterally. The 4 arms are pulled to correct anterior prolapse in a tension-free manner. The AVW is closed with 2-zero Vicryl®.

Cystoscopy was performed as needed in each group. Concurrent procedures such as posterior colporrhaphy and vaginal hysterectomy were done as needed. Apical defects were treated with uterosacral ligament suspension or sacrospinous suspension if point C and D were −3 or greater, or the surgeon identified the need for additional apical support.

Statistical data analysis was done with SAS® for Windows®, version 9.2. To evaluate preoperative differences between the groups we applied the chi-square test for categorical variables, and the Student t-test and Mann-Whitney test for continuous variables. Quantitative data are shown as the mean ± SD. To compare parameters between groups and times we used repeated measures ANOVA. Variables were transformed to ranks due to an absent normal distribution. Multivariate analysis was done using a linear or logistic regression model to study the effect of the group after adjustment for